

CLAIMS

1. A pharmaceutical composition comprising one or more active ingredients selected from the group consisting of an anti-infective agent, anti-inflammatory agent, mucolytic agent, antihistamine, anticholinergic agent, an antileukotriene, a decongestant, and a combination of these classes of agents, said composition being formulated as a liquid in a unit dose for aerosol administration to the nasal sinuses and being packaged with directions for its use in the treatment of sinusitis, and wherein the surface tension of the liquid is less than about 70 dynes/cm.
2. The composition of claim 1, wherein the composition has a pH in the range of about 3.0 to 8.5.
3. The composition of claim 1, wherein the anti-infective agent is selected from the group consisting of an antibiotic, an anti-viral, a non-antibiotic antimicrobial, and an antiseptic.
4. The composition of claim 1, wherein the anti-inflammatory agent is selected from the group consisting of steroid anti-inflammatory agents, non-steroidal anti-inflammatory agents, and mast cell inhibitors.
5. The composition of claim 1, wherein the composition further comprises a compound that lowers the surface tension of the liquid to less than about 70 dynes/cm in addition to the one or more active ingredients.
6. The composition of claim 5, wherein the compound is a surfactant.
7. The composition of claim 1, further comprising a decongestant.

8. The pharmaceutical composition of claim 1, which when administered as an aerosolized spray has minimal systemic side effects.

9. The pharmaceutical composition of claim 1, wherein said active ingredient is an anti-infective agent and the sinusitis is caused by a pathogen selected from the group consisting of Alpha Hemolytic *Streptococci*, Beta Hemolytic *Streptococci*, *Branhamella Catarrhalis*, *Diphtheroids*, *Haemophilus influenzae* (beta-lactamase positive and negative), *Moraxella* species, *Pseudomonas aeruginosa*, *Pseudomonas maltophilia*, *Serratia marcescens*, *Staphylococcus aureus*, *Streptococcus pneumonia*, *Aspergillus*, *Mucor* and *Candida Albicans*, *Fusarium*, *Curvularia*, *cryptococcus*, *coccidioides*, and *histoplasma*.

10. The pharmaceutical composition of claim 9, wherein said anti-infective agent is selected from the group consisting of penicillins, cephalosporins, macrolides, ketolides, sulfonamides, quinolones, aminoglycosides, beta lactam antibiotics, and linezolid.

11. The pharmaceutical composition of claim 6, wherein said surfactant is a polysorbate.

12. A kit containing a pharmaceutical composition of claim 1, and a nebulizer cup with a nasal adapter for delivering the composition in aerosolized form to the nasal sinuses.

13. The combination of a nebulizer device and the kit of claim 12.

14. An aerosol comprising the pharmaceutical composition of claim 1, wherein at least about 85% of the aerosolized particles have a mass median aerodynamic diameter within the range of about 1.0 to 5.0 microns.

15. An aerosol according to claim 14, wherein said aerosol is effective to kill at least about 90% of pathogens causing sinusitis in a patient within about 21 days following an every 8 hr (TID), every 12 hr (BID), or every 24 hr (AD) administration protocol.

16. A method of treating a mammal suspected or diagnosed as having chronic sinusitis comprising the step of administering to the patient the pharmaceutical composition of any one of claims 1 or 2, by aerosolization using a nebulizer which delivers aerosol particles of between about 1 to 5 microns in average diameter.

17. The method of claim 16, wherein the mammal is a human.

18. The method of claim 16, wherein the nebulizer is a PARI nebulizer with a nasal adapter.

19. The method of claim 16, wherein the nebulizer is connected to a PARI SinuNEB compressor.

20. The method of claim 16, wherein the nebulizer delivers a majority of aerosolized particles in the size range of about 2.0 to 4.0 microns in diameter.

21. The method of claim 16, wherein the pharmaceutical composition is administered to the patient 1-3 times a day for a total of 7-28 days.

22. The pharmaceutical composition of claim 10, wherein the polysorbate is selected from the group consisting of polysorbate 20 to polysorbate 85.

23. The composition of claim 3, wherein the antibiotic is selected from the group consisting of cefuroxime, ciprofloxacin, amphotericin B, ofloxacin, and tobramycin.

24. The composition of claim 3, wherein the non-antibiotic antimicrobial is taurolidine.

25. The composition of claim 3, wherein the antiseptic is iodine or a salt thereof.

26. The composition of claim 1, wherein the antileukotriene is montelukast.

27. The composition of claim 1, wherein the antihistamine is loratadine.

28. The composition of claim 1, wherein the active ingredients are a combination of antibiotics comprising gentamicin and cefuroxime or cefoperazone and oxymetazoline.

29. The pharmaceutical composition of claim 1, wherein the surface tension is less than about 50 dynes/cm.

30. The pharmaceutical composition of claim 1, wherein the surface tension is between about 10 to 40 dynes/cm.

31. A pharmaceutical composition comprising one or more antifungal agents, said composition being formulated as a liquid in a unit dose for aerosol administration to the nasal sinuses and being packaged with directions for its use in the treatment of sinusitis, and wherein the surface tension of the liquid is less than about 45 dynes/cm.

32. The pharmaceutical composition of claim 31, wherein the surface tension is between about 10 to 40 dynes/cm.

33. The pharmaceutical composition of claim 31, wherein the antifungal agents are selected from the group consisting of amphotericin B, and azole antifungals.

34. An aerosol comprising the pharmaceutical composition of claim 31, wherein at least about 85% of the aerosolized particles have a mass median aerodynamic diameter within the range of about 1.0 to 5.0 microns.

35. A method of treating a mammal suspected or diagnosed as having chronic sinusitis comprising the step of administering to a patient the pharmaceutical composition of claim 31, by aerosolization using a nebulizer which delivers aerosol particles of between about 1 to 5 microns in average diameter.

36. A method of treating nasal or sinus polyps comprising administering to a patient the composition of claim 1.

37. The method of claim 36, wherein the composition comprises a steroid anti-inflammatory and a diluent.

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